

Exhibit B

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF ARIZONA

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5 -----
6)
7 IN RE BARD IVC FILTERS)
8 PRODUCTS LIABILITY) NO. MD-15-02641-PHX-DGC
9 LITIGATION,)
10)
11 -----

12 DO NOT DISCLOSE
13 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

14
15 VIDEOTAPED DEPOSITION
16 - of -

17 CHRISTOPHER S. MORRIS, M.D.

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19
20 taken on behalf of the Plaintiffs on Tuesday,
21 July 25, 2017, at the Courtyard by Marriott,
22 25 Cherry Street, Burlington, Vermont,
23 commencing at 9:08 AM.
24

25 VIDEO TECHNICIAN: DEVYN MULHOLLAND
26 COURT REPORTER: JOHANNA MASSÉ, RMR, CRR

1 A. Yes.

2 Q. What level of certainty did you apply to your
3 opinions?

4 MR. ROGERS: Object to the form.

5 You can respond.

6 A. I don't know really how to answer that
7 question. I think that's more of a legal term, as far
8 as I can tell, but I approached this litigation the
9 same way I practice interventional radiology on a daily
10 basis. I always seek the truth, number one. I use
11 many factors to help render my opinions. That includes
12 first and foremost my personal experience, which I
13 consider large. I also review the medical literature,
14 the pertinent medical literature, of which there's not
15 a lot of Level I or Level II evidence related to IVC
16 filters, unfortunately, and I'm -- I'm part of that
17 problem. I've contributed to the Level III and below
18 evidence as well.

19 But I still use the literature to help me
20 make -- make these decisions. I attend national
21 meetings, talk with colleagues, participate in journal
22 clubs, and honestly rely a lot on the FDA to -- to help
23 make these decisions as well. So there are lots of
24 different factors that go into it.

1 Q. Right. So --

2 A. My -- I approach the litigation using the
3 same -- same methodology, essentially. So I would say
4 a high level of certainty.

5 Q. Right. So I understand your answer was mostly
6 about your methodology, your approach, what things
7 you -- how you approach reaching a decision, and I'm --
8 and I think the last part of your answer where you said
9 "so I would say a high level of certainty," that's
10 really what I was getting after with my question is
11 what level of certainty, and you said a high level of
12 certainty.

13 So my question follow-up on that is, Did
14 you --

15 A. I was going to say the reason I said all those
16 is because if I just relied on a hunch or what my
17 pulmonology colleague told -- told me that had never
18 placed a filter in his life, that methodology would
19 lead me to have less of a high level of certainty.

20 Q. Of course.

21 A. I might have a low -- so that's why I had to
22 give you the background on how I know that I reached a
23 high level of certainty in my opinions.

24 Q. Yes. And so if you were to put a numerical

1 quantification to "high level of certainty," would it
2 be -- what would it be, approximately?

3 MR. ROGERS: Object -- object to the form.

4 A. That is a very difficult question to answer,
5 quant- --

6 Q. You're getting paid \$500 an hour to answer
7 hard questions.

8 A. Well, yeah.

9 MR. ROGERS: Object to the form. That's not
10 the definition --

11 MR. ROTMAN: I'll strike that.

12 MR. ROGERS: -- of what makes a question
13 acceptable.

14 MR. ROTMAN: I'll strike that. I'll strike
15 that.

16 Q. Maybe you can't answer it.

17 A. I mean, you know, the -- so --

18 Q. What level of --

19 A. -- I have to -- I have to answer that
20 difficult question with a difficult answer. And, you
21 know, we were talking on a break a little while ago
22 about memory issues. My -- my benchmark for 100
23 percent certain medical science, so to speak my
24 touchstone, is my brother, who I'm very close to, who's

1 a top ten neuroscience researcher specializing in
2 Alzheimer's and memory disorders, so I gauge that as
3 being 100 percent certain. He has \$50 million in
4 grants. He's the quintessential medical scientist that
5 relies on Level I and Level II evidence. So when I
6 compare his body of work, which I know -- which I've
7 been following my entire life -- again, he's -- you
8 know, he's very close to me and -- and I really respect
9 his degree of scientific validity. When I compare that
10 to the literature that's available regarding IVC
11 filters, there's basically no -- no comparison, so how
12 can I make 100 percent certain opinions based on
13 literature which is less than Level I or Level II
14 evidence?

15 Q. Understood. And -- and so nevertheless, you
16 have reached opinions --

17 A. Yes, I --

18 Q. -- and you had -- and in order to do that, you
19 had to reach a certain point based on your review of
20 the evidence where you had a high level of certainty;
21 that's what you testified. And I'm trying to
22 understand how to understand what you mean by "high
23 level of certainty." So, for example, I asked you for
24 a numerical and I don't -- and I didn't get an answer

1 Q. Potentially, but possibly not, right?

2 A. It could potentially work its way out or it
3 could go the other way and lodge in the
4 retroperitoneum.

5 Q. Right. So focusing on that specific scenario,
6 we have a fracture. Let's assume it's asymptomatic.
7 Patient doesn't feel any pain, doesn't come to the
8 doctor and complain about anything, and it's embedded.
9 One possibility, weeks later, months later, years
10 later, is that it breaks loose and goes in the
11 direction of the heart. Right?

12 A. That would be rare, but that could happen,
13 yes.

14 Q. Right. And -- and so certain asymptomatic --
15 certain number of asymptomatic fractures can become
16 life-threatening problems based on that dynamic of the
17 blood flow in the vessel and -- and breaking loose
18 from -- from the -- from the fractured element being
19 embedded in -- in the tissue, right?

20 MR. ROGERS: Object to the form.

21 A. We believe that's a rare event, but that could
22 happen, yes.

23 Q. And you read the -- the editorial that
24 accompanied the publication of the Nicholson study by

1 organs and cause death or other serious injuries,
2 right?

3 A. Well, one -- by that logic, migrating into the
4 retroperitoneum would be better than migrating
5 centrally into the blood flow and then embolizing to
6 the heart, so it depends which migration we're -- we're
7 trying -- we're discussing.

8 Q. But you don't want it to migrate to the heart,
9 right?

10 A. That would be the least -- the least favorable
11 location, correct.

12 Q. Where else would you not want it to migrate
13 to?

14 A. I mean, theoretically the pulmonary artery,
15 but that is even, I think, a rarer location to -- that
16 it would -- for it to cause a complication.

17 Q. And why is it that you would not want a filter
18 strut to migrate to the heart? What could happen
19 that's not good?

20 A. That's not good? Because I think the majority
21 of times -- nothing happens the majority of times.
22 Rarely it can perforate the wall of the heart and
23 extend into the pericardium and cause either a
24 pericardial effusion or -- or hemorrhagic effusion - we

1 call it tamponade - or an infection theoretically.

2 Those are extremely rare events, but that could
3 potentially happen.

4 Q. And then what happens to the patient when that
5 happens?

6 MR. ROGERS: Object to the form.

7 A. It theoretically could be a fatal event, but I
8 think that is an extremely rare situation.

9 Q. And why would it be fatal? How could it be
10 fatal?

11 A. Well, tamponade -- remember, this -- this wire
12 is very small caliber.

13 Q. It's like a needle, right?

14 A. That's right. Needle. And it is -- I'm
15 sorry. What was the -- what was your question again?

16 Q. Why would it be fatal? How could it be fatal?

17 A. Oh, theoretically --

18 MR. ROGERS: Object to the form.

19 A. -- it could cause bleeding. But I'd like to
20 take that into consideration and compare that to
21 techniques that interventional radiologists used all
22 the time, including my father, who put catheters a
23 hundredfold larger directly into the left ventricle to
24 do coronary -- cardiac angiography prior to modern

1 techniques and simply pulled them out when they were
2 done and put a Band-Aid on the skin, and the vast
3 majority of those patients had no complication at all.
4 So I'm trying to explain the difference between a tiny,
5 tiny-caliber needle perforating the wall of the heart
6 and a large-caliber tube perforating the heart.

7 MR. ROTMAN: So I move to strike the
8 nonresponsive portion.

9 Q. But if you could look at the next -- the --
10 the right column of the page that we're on in this
11 exhibit, and the sentence starting on line two
12 beginning with the word "Assuming." Do you see that?

13 A. Yes.

14 Q. And read along with me, if you would.
15 "Assuming that our data do not represent a statistical
16 aberration, we suggest there are many other patients
17 with Recovery filters with arm fractures and migrations
18 in whom it is conceivable that these migrated fragments
19 have gone undetected."

20 Okay? So I want to ask a question about your
21 understanding of what -- how it could be that fractures
22 and migrations could go undetected.

23 A. Because most of the time they're asymptomatic,
24 so the patient's not going to have any symptom and

1 we'll never know that they even have a fragment until
2 someone tells them based on a chest x-ray or some kind
3 of scan that they have a fragment there, and in my
4 experience, all of a sudden those patients then do
5 develop symptoms because now they know they have a
6 fragment.

7 Q. But as we established before, asymptomatic
8 fractures and migrations can become life-threatening
9 events?

10 A. Rarely.

11 Q. Rarely. In your opinion, rarely?

12 A. I emphasize rarely.

13 Q. Okay. Now, I want to -- I want to talk about
14 how it could be that -- how it would present, this
15 scenario that you describe where the patient could die
16 from the -- from the needle in the heart, if you would,
17 causing tamponade and bleeding and that -- that series
18 of adverse events.

19 Let's assume a patient is at home with a Bard
20 retrievable filter that was implanted eight years ago
21 and -- this sequence of events in fact happened. And
22 they're home, they're not in the hospital, they're not
23 in a doctor's office, and they wake up dead; in other
24 words, they -- this all happens and they die. Okay?

1 Q. Right. And you don't know as you sit here
2 today whether that's happening all over the place every
3 day or every week in this country and it's not being
4 recognized but filter fractures are killing people and
5 they're dying at home and nobody's connecting it to the
6 filter?

7 MR. ROGERS: Object to -- object to the form
8 and foundation.

9 You can respond.

10 Q. Did you just laugh?

11 A. Well, I'm trying to think of the scenario. I
12 mean, that -- people die from many different reasons.
13 That's, like, a negative question you're asking me, so
14 how can I prove a negative if there's no evidence on a
15 negative?

16 Q. You can just answer my question, which was,
17 You don't know as you sit here today whether this is
18 happening frequently and not being detected?

19 A. I don't know that --

20 MR. ROGERS: Object to the form.

21 Q. Right?

22 A. I don't know that it is; I don't know that it
23 isn't.

24 Q. Right. And so you cannot say to a reasonable

1 degree of scientific certainty that this event is rare
2 unless you know the answer to the question of whether
3 it's recognized when it happens on a regular basis,
4 right?

5 MR. ROGERS: Object to the form.

6 A. It's speculation.

7 Q. You don't know if it's rare or not, do you?

8 MR. ROGERS: Object to the form.

9 A. I -- that's really difficult to answer because
10 we know from some of these observational studies that
11 have filter fragments in their chest, the vast majority
12 of them are asymptomatic and they're not reporting
13 large numbers of deaths in their patient population,
14 so --

15 Q. Now, in the middle paragraph of this Hull
16 paper, you see that in addition to evaluating
17 whether -- the condition of the filter, they were
18 looking at these fractured filter parts under a
19 scanning electron microscope, right?

20 A. Yes.

21 Q. And they did so and they made a determination
22 that it looked like to them bending fatigue fractures,
23 right?

24 A. That's what they say, yes.

1 Did I read that correctly?

2 A. Yes.

3 Q. So what does that mean?

4 A. It means that in a patient that has a fragment
5 embolization and if they develop chest pain, clinicians
6 evaluating the chest pain may be driven to evaluate
7 them for coronary artery disease, which is much more
8 common and a much more common cause of sudden death
9 than a fractured filter component embolization.

10 Q. And you agree that that -- with that
11 statement?

12 A. Yeah. And I certainly would think that that's
13 warranted also because it is so much more common.

14 Q. But that very statement tells you to the
15 extent that that's the case that there will be
16 unrecognized patient deaths from filters.

17 MR. ROGERS: Object to the form.

18 Q. Because patients are having cardiac
19 embolization and it's misdiagnosed --

20 A. Well --

21 Q. -- as something else.

22 MR. ROGERS: Object to the form.

23 Q. That's what this is saying, isn't it?

24 A. I'm still looking for a proven case of a

1 filter fragment embolization that's caused a death.
2 Maybe there is. Maybe you know of one, but I
3 haven't -- I haven't seen that in the literature or a
4 case report of that, a proven case. I know Nicholson
5 talked about sudden death at home, but again, there was
6 no documentation that I could see that an autopsy
7 proved that that was the cause of death. So I don't
8 know what -- I don't know if it's frequent or not. I'm
9 just saying I haven't seen any evidence to say that it
10 is or isn't.

11 Q. I didn't say it was frequent. My question
12 wasn't about whether it's frequent. My question was
13 about whether these -- this statement is saying that
14 people presenting with this problem are going -- are --
15 are frequently, commonly misdiagnosed, right?

16 MR. ROGERS: Object to the form.

17 A. It's speculation, but that's a possibility.

18 Q. In other words, the statement that you've made
19 several times today about it being a rare event assumes
20 that the events are being identified. You don't --
21 otherwise you don't know whether it's rare or not,
22 right?

23 MR. ROGERS: Object to the form.

24 A. I think some of these observational studies

1 have shown fracture fragments in -- in numbers of their
2 patients, and they have generally been asymptomatic,
3 according to the papers. The Vijay article, for
4 instance.

5 Q. Asymptomatic at one point in time.

6 A. True.

7 Q. Not necessarily remaining that way, right?

8 A. No one knows what happens 20 years from now,
9 correct.

10 Q. So a patient comes to see you and you see that
11 there's a fracture and they're saying, Well, I don't
12 feel any pain. And you say, Okay, well, go home; come
13 back in a year? Or do you say, Let's talk about what
14 can happen and what we might do for you?

15 A. That has not been a scenario I have seen
16 recently. My partner, though, did a month or two ago,
17 and he did evaluate that patient in the clinic, also
18 consulted our cardiothoracic surgeon, and they all
19 agreed that that patient was asymptomatic and would
20 just be followed clinically and that no attempt at
21 removing that fragment would be made or indicated at
22 that time.

23 Q. That would be a patient decision to be made in
24 consultation with their doctor, right?

1 A. Yes.

2 Q. And did you review the report of Dr.
3 Eisenberg?

4 A. Yes.

5 Q. And do all those reports that I just mentioned
6 cite and quote extensively from various Bard internal
7 documents?

8 A. And much of -- yes. And much of the verbiage
9 is identical among all those reports.

10 Q. And in any of those reports, after reviewing
11 what those experts had to say about those internal
12 documents, did they change any of the opinions that you
13 have in this case?

14 A. No.

15 Q. Doctor, you were asked several questions by
16 plaintiffs' counsel where you were given hypotheticals
17 about filter fragments traveling to the heart and
18 causing possible consequences. Do you recall that?

19 A. Yes.

20 Q. And in your practice have you ever seen that
21 occur?

22 A. Rarely, yes.

23 Q. And -- and so when you were testifying about
24 those various scenarios, were you testifying about that

1 as a hypothetical situation?

2 A. Only, yes.

3 Q. And when you say "rarely," can you give us
4 some sense of what that means?

5 A. Well, we've -- this is my best estimate that
6 we've placed roughly 1,000 Bard retrievable filters
7 over the years and we've removed -- I should know the
8 exact number, but it's somewhere between -- at least
9 300 -- actually, it's probably now more -- you know,
10 closer to -- over 300 of those filters, and we've only
11 encountered four fractures of a Bard filter. We've
12 seen other fractures of some of the other filters we've
13 placed. And I only know of two cases where there
14 was -- where there -- where there were fragments in the
15 chest, one in the right ventricle and another in the --
16 several fragments in the pulmonary arteries.

17 Q. Doctor, to shift gears on you a little bit, do
18 you recall being asked by plaintiffs' counsel to -- you
19 were asked several questions asking you to quantify the
20 level of certainty that you were giving for your
21 opinions in this case. Do you recall that?

22 A. Yes.

23 Q. And prior to today, have you ever been asked
24 in the course of your career to quantify the level of